K043257/S1
#1 of 3

FEB - 3 2005

Boston Scientific

1. 510(k) Summary

a. General Information

Modified Device Information

Category:	Comments:
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Correspondent:	Todd G. Brill Senior Specialist, Regulatory Affairs Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Contact Information:	E-mail: brillt@bsci.com Phone: (408) 895-3564 Fax: (408) 895-2202
Device Common Name:	Signal Acquisition Module (SAM)
Device Proprietary Name:	Arrhythmia Mapping System with Real-time Position Management (RPM™)
Device Classification:	21 CFR §870.1220

Predicate Device Information

Predicate Device:	Arrhythmia Mapping and Tracking System (K992912)
Predicate Device Manufacturer:	Boston Scientific Corporation
Predicate Device Common Name	Signal Acquisition Module (SAM)
Predicate Device Classification:	21 CFR §870.1220
Predicate Device Classification Number:	Class II

b. Date Summary Prepared

January 13, 2005

c. *Description of Device*

Signal Acquisition Module (SAM): One of three main components of the RPM™ System that includes the Arrhythmia Mapping Computer (AMC) and the Position Acquisition Module (PAM). The SAM is an amplifier that filters cardiac signal data and transfers it to the AMC for processing and display. The SAM collects the following input signals, applies gain and filter settings as programmed through the Mapping System software and transfers them to the computer over the fiber optic data link for further processing and display.

1. one or more standard EP catheter electrodes (up to 48 catheter inputs)
2. two pacing inputs from an external pacing stimulator, which the Mapping System software can route to any catheter bipole or unipole
3. a synch output channel that can be used with pacing stimulators to synchronize pacing inputs
4. a 12-lead EKG
5. two pressure transducer inputs
6. One 64 electrode Constellation™ Catheter or up to 64 individual catheter inputs through bedside Expansion Pods

d. *Intended Use*

The Boston Scientific Tracking diagnostic catheters are indicated for cardiac electrophysiological mapping and delivering pacing stimuli. In addition, the Tracking and Reference Catheters are used with the Real-time Position Management (RPM™) System to provide catheter location information.

The Signal Acquisition Module (SAM) is a component of the RPM™ System and supports the above indication.

e. *Comparison to Predicate Device*

The Modified Signal Acquisition Module (SAM) has the same intended use as the predicate device and was validated to perform as the original device without the

options of choosing a system reference for the catheters. The modified device makes sole use of the Driven Right Leg Reference.

Table 1 - Comparison of Device Characteristics to Predicate

Component	Arrhythmia Mapping and Tracking System K992912	Real-time Position Management (RPM™) K043257
Signal Acquisition Module (SAM)	64 Channel Signal Processing Unit ➢ 48 Intra-cardiac ➢ 12 EKG ➢ System Reference - EKG Input - 2 Options o Catheter Reference o Right Leg Reference ➢ 2 Pressure ➢ 2 Pacing ➢ Dynamic Diode - Minimize Pacing Artifacts ➢ Post Pace Blanking Interval - Software to support Dynamic Diode	128 Channel Signal Processing Unit: ➢ 112 Intra-cardiac ➢ 12 EKG ➢ System Reference - Driven Right Leg ➢ 2 Pressure ➢ 2 Pacing ➢ Dynamic Diode - ***Removed*** ➢ Post Pace Blanking Interval - ***Removed***

f. Summary of the Non-clinical Data

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP)). Specifically, non-clinical tests conducted for the Device showed the device met its design-input criteria, and was safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Boston Scientific Corporation
c/o Mr. Todd Brill
Senior Specialist, Regulatory Affairs
2710 Orchard Parkway
San Jose, CA 95134

Re: K043257
Trade Name: Real-Time Position Management (RPM™) System
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II (two)
Product Code: DRF
Dated: January 12, 2005
Received: January 14, 2005

Dear Mr. Brill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043257

Indications for Use

510(k) Number: K043257

Device Name: Real-time Position Management (RPM™)

Indications for Use:

The Boston Scientific Tracking diagnostic catheters are indicated for cardiac electrophysiological mapping and delivering pacing stimuli. In addition, the Tracking and Reference Catheters are used with the Real-time Position Management (RPM™) System to provide catheter location information.

Prescription Use ✓ AND/OR Over-the-Counter Use _____
(Part 21CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043257